Actions on Draft NTP Technical Reports Peer Reviewed at the NTP Technical Reports Peer-Review Meeting

May 22, 2014

The NTP convened the NTP Technical Reports Peer-Review Panel on May 22, 2014, to peer review four draft NTP Technical Reports. Summary minutes will be prepared and posted to the NTP website when completed (http://ntp.niehs.nih.gov/go/36144). The Panel peer reviewed each report and provided its opinion on the draft NTP conclusions regarding the levels of evidence of carcinogenic activity for the substances tested. The Panel's recommendations do not necessarily represent the opinion of the NTP. The NTP will consider the input from the Panel in finalizing the technical reports. When completed, the technical reports will be published on the NTP website (http://ntp.niehs.nih.gov/go/reports).

TR-585: Green Tea Extract

The Panel voted (5 yes, 1 no, 0 abstentions) to:

- Accept as written, the draft NTP conclusions, no evidence of carcinogenic activity of green tea extract in male and female Wistar Han rats and in male B6C3F1/N mice.
- Recommend the conclusion, no evidence of carcinogenic activity of green tea extract in female B6C3F1/N mice, because the Panel disagreed with the NTP conclusion that occurrences of squamous cell neoplasms (squamous cell papilloma or squamous cell carcinoma) of the tongue may have been related to treatment.

TR-584: Indole-3-carbinol

The Panel voted (4 yes, 2 no, 0 abstentions) to accept, as written, the draft NTP conclusions, no evidence of carcinogenic activity of indole-3-carbinol in male Harlan Sprague Dawley rats, some evidence of carcinogenic activity of indole-3-carbinol in female Harlan Sprague Dawley rats, clear evidence of carcinogenic activity of indole-3-carbinol in male B6C3F1/N mice, and no evidence of carcinogenic activity of indole-3-carbinol in female B6C3F1/N mice.

TR-586: CIMSTAR 3800

The Panel voted (6 yes, 0 no, 0 abstentions) to:

- Accept as written, the draft NTP conclusions, equivocal evidence of carcinogenic activity of CIMSTAR 3800 in female Wistar Han rats, no evidence of carcinogenic activity of CIMSTAR 3800 in male B6C3F1/N mice, and some evidence of carcinogenic activity of CIMSTAR 3800 in female B6C3F1/N mice.
- Accept the draft NTP conclusion, equivocal evidence of carcinogenic activity of CIMSTAR 3800 in male Wistar Han rats, and recommend removing the incidences of benign or malignant granular cell tumors (combined) of the brain as part of the evidence for the conclusion based on: (1) the lack of dose response for benign or malignant granular cell tumors (combined) of the brain in the male Wistar Han rats, (2) the lack of granular cell tumors in the historical control data is not informative as there are not adequate numbers of animals in the historical control to detect the background occurrence of this low

incidence tumor, and (3) there were two incidences of granular cell tumors in the chamber controls of female Wistar Han rats.

TR-583: Bromodichloroacetic Acid

The Panel voted unanimously (6 yes, 0 no, 0 abstentions) to:

 Accept the draft NTP conclusion, clear evidence of carcinogenic activity of bromodichloroacetic acid in male F344/NTac rats, and recommend that the increased incidences of glioma or oligodendroglioma (combined) of the brain and the increased incidences of squamous cell papilloma or squamous cell carcinoma of the oral cavity (oral mucosa or tongue) may have been related to treatment instead of were related to treatment.

The Panel voted unanimously (6 yes, 0 no, 0 abstentions) to:

 Accept the draft NTP conclusion, clear evidence of carcinogenic activity of bromodichloroacetic acid in female F344/NTac rats, and recommend that the increased incidences of glioma or oligodendroglioma (combined) of the brain may have been related to treatment instead of were related to treatment.

The Panel voted unanimously (6 yes, 0 no, 0 abstentions) to:

• Accept the draft NTP conclusions as written, clear evidence of carcinogenic activity of bromodichloroacetic acid in male B6C3F1/N mice, and clear evidence of carcinogenic activity of bromodichloroacetic acid in female B6C3F1/N mice.